510(K) SUMMARY

JUN - 8 2012

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92(a).

SUBMITTER'S NAME, ADDRESS, TELEPHONE NUMBER, CONTACT PERSON, AND DATE SUMMARY PREPARED

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DATE SUMMARY PREPARED: January 20, 2012

NAME OF DEVICE, INCLUDING TRADE NAME AND CLASSIFICATION NAME

a. Trade/Proprietary Name: LensAR Laser System - fs 3D (LLS-fs 3D)
b. Common/Usual Name: LensAR Laser System - fs 3D
c. Classification Name: Ophthalmic Laser, Phacofragmentation System
d. Classification Code(s): 21 CFR 886.4390 OOE; 21 CFR 886.4670 HQC

PREDICATE DEVICES

510(K) #	TRADE NAME	MANUFACTURER
K112098	LensAR-fs Laser System	LensAR, Inc.
K090633 and K102727	LensAR Laser System	LensAR, Inc.

DEVICE DESCRIPTION

The predicate LensAR Laser System is an ophthalmic surgical laser that has been cleared for use in anterior capsulotomy in cataract surgery (K090633) and anterior capsulotomy and laser phaco fragmentation performed individually or consecutively during the same surgery (K102727). A new laser device with modification to the pulse width of the laser (LensAR-fs Laser System) was cleared by the Agency under K112098 for the same indication for use.

The LensAR Laser System - fs 3D (LLS-fs 3D) employs a mode-locked Yb:YAG laser which generates a high frequency series of femtosecond, low energy pulses at a wavelength of 1030 nm. The system is technologically the same as the predicate device defined in K112098, i.e., designed to cut the lens and lens capsular tissue, with minimal collateral damage, by the mechanisms of plasma mediated ablation and photodisruption of targeted tissue at the beam focus. The precision capsulotomy and lens fragmentation incision patterns are generated by computer-controlled scanning of the position of the laser beam focus in three dimensions at the target location. The laser energy is delivered to the eye through a disposable, proprietary patient interface device (PID) that consists of a Suction Ring which is affixed to the eye, and a precision fused silica window, which when mounted onto a PID Arm, fixates the eye and allows the laser light to be coupled into the eye through a refractive index matching cell. The index matched light coupling allows the focused laser pulses to be accurately delivered to target locations within the patient's crystalline lens.

STATEMENT OF INTENDED USE

The LensAR Laser System - fs 3D (LLS-fs 3D) is indicated for anterior capsulotomy and laser phaco fragmentation during cataract surgery. The anterior capsulotomy and laser phaco fragmentation procedures may be performed either individually or consecutively during the same surgery.

TECHNOLOGICAL CHARACTERISTICS COMPARISON

The femtosecond laser system, including pulse energy control and monitoring, used in the LLS-fs 3D is the same as that used in the predicate device LLS-fs. The software used to generate the custom incision patterns and the shot/incision patterns in the current and predicate device are essentially unchanged. The essential components of the beam delivery system are also unchanged.

The LLS-fs 3D is of comparable type and is substantially equivalent to the following predicate devices:

510(k) Number	Clearance Date	Device Description
K090633 Anterior Capsulotomy	05/13/2010	Technology and Indications for Use predicate device
K102727 Anterior Capsulotomy & Laser Phaco Fragmentation	03/16/2011	LensAR Laser System – Anterior Capsulotomy & Laser Phaco Fragmentation
K112098 Anterior Capsulotomy & Laser Phaco Fragmentation	10/19/2011	LensAR-fs Laser System (LLS-fs)

- The activities used to evaluate the LensAR Laser System - fs 3D (LLS-fs 3D) and the information and reports provided in this 510(k) submission do not identify any new issues of safety or effectiveness. The optical radiation hazard analysis

confirms the continuing ocular safety equivalence to the predicate device detailed in 510(k) K102727 and K112098 for the predicate devices.

- The LLS-fs 3D Laser technology and mechanism of laser-tissue interaction are unchanged from that of the femtosecond laser (K112098) identified in the table above.
- The indication for use statement for anterior capsulotomy and laser phaco fragmentation for the LLS-fs 3D is the same as that of the predicate devices detailed in the table above.
- The differences between the LLS-fs 3D and the predicate devices are insignificant and do not affect the safety or effectiveness of the device.

The LensAR Laser System - fs 3D (LLS-fs 3D) and predicate LLS-fs both include the following key elements:

- a femtosecond laser system to generate laser pulses for the laser incision process,
- a control system which generates custom shot patterns based on the biometrics system measurement of the eye and controls a beam delivery system,
- a beam delivery system to focus the pulses to the predetermined pattern of contiguously placed pulses to generate the laser incisions in the lens,
- a means to immobilize and "dock" the eye to the system,
- a biometric system to measure the position and shape of the crystalline lens relative to the system.

The femtosecond laser system used to generate the laser pulses and pulse energy control and monitoring systems are the same for the LLS-fs 3D and the predicate device. The software control system which generates the custom shot patterns for the laser incisions, based on the biometric system measurements, and which controls the beam delivery system, are the same in both devices, except for minor software modifications. The laser incision patterns are identical to those used in the predicate device. The beam delivery system in the LLS-fs 3D uses exactly the same ScanLab galvo system, variable telescope, scanning lens, electronics and control software as used in the predicate device.

The LLS-fs 3D incorporates improvements to the design of the docking/patient interface device and the biometric system, compared to the predicate LLS-fs. The LLS-fs 3D and predicate system both introduce light into the eye through a fused silica plate and saline bath which matches the refractive index of the cornea to reduce distortion of the laser beam by the curved cornea to improve the quality of laser incisions. Both also dock the laser to the eye using a suction ring incorporating a suction seal and vacuum source to immobilize the eye. The same suction seal geometry and vacuum pressure is used in both devices. The LLS-fs 3D design eliminates a curved plastic corneal contact lens present in the predicate device. The contact lens had no role optically or in immobilizing the eye.

Like the LLS-fs, the LLS-fs 3D uses a biometric system to measure and construct a three dimensional model of the optical surfaces within the eye. Both devices employ a scanning light source to successively illuminate a number of longitudinal sections of the eye at different angles, image the illuminated sections with an off-axis Scheimpflug camera and ray trace back from the images to determine the locations of various optical

surfaces. The LLS-fs 3D biometric system uses a larger number of longitudinal sectional images to measure the optical surfaces more comprehensively than is used in the LLS-fs; and the scanning illumination in the LLS-fs 3D is optimized for each optical surface within the eye to improve the clarity and contrast of the images.

BRIEF SUMMARY OF PERFORMANCE TEST RESULTS

The performance data supporting substantial equivalence of the LensAR Laser System - fs 3D to the predicate LensAR-fs and LensAR devices are summarized as follows:

- Testing of accuracy and precision of the biometric and beam delivery systems was performed using *ex vivo* porcine and human donor eyes and custom built artificial eyes. Further testing of test patterns in acrylic plastic was performed to ensure that shot placement accuracy for individual shots and lines and rings of shots was the same as that of the predicate device.
- Evaluation of the fit and function of the enhanced proprietary Patient Interface Device and the ability of the 3D-CSI system to appropriately image the target intraocular surfaces of interest was demonstrated in an evaluation which confirmed the performance of the LLS-fs 3D as substantially equivalent to that of the predicate devices.
- An analysis of the optical radiation hazard to non-target tissue demonstrated that the LLS-fs 3D femtosecond laser, biometric system scanning diode light source and patient eye illumination (light emitting diodes) are eye safe under all normal operating and known fault conditions.
- Sterilization and packaging testing of the disposable PID using gamma radiation to ensure a sterility assurance level of 10^{-6} was completed. Functional testing after gamma irradiation was demonstrated. The method of cleaning and autoclaving the reusable PID Arm was validated.
- The biocompatibility testing on all parts of the disposable Patient Interface Device which directly contacts or indirectly contacts through a fluid interface any eye tissue was performed for: cytotoxicity, irritation, sensitization, and chemical and physical characteristics. No biocompatibility issues were found in the testing.
- The Thermal and Acoustic effects remain unchanged from that reported in 510(k) K102727 and K112098. The LLS-fs 3D laser tissue interaction characteristics and capsular tensile strength remain unchanged from that of the LLS-fs Laser (K112098).
- As demonstrated in K112098 for the LLS-fs Laser, the tensile strength characteristics of the anterior capsule button cut with the LLS-fs are consistent with the results seen in the same experimental test model as was reported in 510(k) K090633 for the LensAR-ps Laser. The LLS-fs 3D laser tissue interaction characteristics remain unchanged from that of the LLS-fs Laser (K112098).
- A hazard analysis of all potential hazards to the patient, surgeon and other system operators was performed to consider all changes between the LLS-fs 3D and predicate LLS-fs devices. The hazard analysis demonstrates that all potential hazards have acceptable levels of probability/severity characteristics.

- Consistent with the predicate devices Indication for Use (K102727 and K112098), the LensAR Laser System – fs 3D was studied for the indication of anterior capsulotomy and laser phaco fragmentation during cataract surgery. The anterior capsulotomy and phaco fragmentation procedures may be performed either individually or consecutively during the same surgery.
- As anticipated, the adjunctive use of ultrasound for this study was not significantly different from that of the LensAR Laser cohort across the cataract grades. However, as compared to the Control Cohort in K102727 (that used conventional procedures of CCC and ultrasound for lens fragmentation) there was a significant reduction in CDE required for eyes in the LLS-fs 3D Laser cohort with nuclear cataract Grades 2-4. In addition, in the LLS-fs 3D Laser cohort, Grade 5+ cataract cases showed an adjunctive use of ultrasound approximating that of the K102727 Control cohort for Grade 4 nuclear cataracts. In each of the cases with any capsule complications, the event was documented to be associated with irrigation aspiration, ultrasound fragmentation or IOL placement procedures, not with the laser procedures, consistent with the experience of the prior model LensAR Laser as reported in K102727.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

LensAR, Inc.
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Regulatory Consultant
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Orlando, FL 32826

JUN - 8 2012

Re: K120214
Trade/Device Name: Lensar Laser System – fs 3D (LLS-fs 3D)
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: OOE, HQC
Dated: June 1, 2012
Received: June 4, 2012

Dear Ms. McGarvey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K120214

Device Name: LensAR Laser System - fs 3D (LLS-fs 3D) for Anterior Capsulotomy and Laser Phaco Fragmentation

Indications for Use: The LensAR Laser System - fs 3D (LLS-fs 3D) is indicated for anterior capsulotomy and laser phaco fragmentation during cataract surgery. The anterior capsulotomy and laser phaco fragmentation procedures may be performed either individually or consecutively during the same surgery.

Prescription Use: X And/Or Over-the-Counter Use: _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark C Callaway for DLK

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K120214